# VERIFICATION

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# Anchoring Element for Use in Spine or Bone Surgery and Method for Production Thereof

The present invention relates to an anchoring element for use in spinal or bone surgery according to the preamble of Patent Claim 1 and a method for the manufacture thereof.

An anchoring element according to the preamble of Patent Claim 1 is known, e.g. from US 5,005,562 in the form of a monoaxial bone screw and from DE 43 07 576 C1 in the form of a polyaxial bone screw. The known anchoring elements comprise a receiving part for the reception of a rod connecting several anchoring elements of this type, a screw element that is monoaxially or polyaxially connected to the receiving part, and an internal screw that is to be screwed in between the legs of the receiving part and serves for the fixation of the rod. The receiving part according to DE 43 07 576 C1 further comprises an external screw nut for additional fixation that can be screwed onto the receiving part.

In the known anchoring elements, the internal thread or external thread of the receiving part comprise a thread runout. The distance between the rod rest within the receiving part and the thread runout is smaller than the diameter of the rod to be received. This ensures that the internal screw or the external screw nut can exert a sufficient clamping force on the rod.

For a given rod diameter, the length of the free legs of the receiving part and thus the overall height of the anchoring element from the rod rest is determined by the distance on which the internal and/or external thread is provided to ensure reliable fixation. In the area of the thread runout, which may include more than one thread tooth, the depth of the thread diminishes and

the profile of the thread teeth is poorly defined. In order to provide for sufficiently firm attachment of the internal screw or external screw nut, it must be ensured that a sufficient number of turns of thread with a deep profile are present. Therefore, it is necessary either to place the thread runout sufficiently far down in the direction of the rod rest or a corresponding number of turns of thread with a deep profile must be provided upwards in the direction of the free end of the legs which increases the overall height.

Moreover, the manufacture of the thread with a thread runout is resource-consuming from the point of view of manufacturing technology.

Thus it is an object of the present invention to provide an improved anchoring element of the type described above which is easy to manufacture and has a reduced overall height, but provides the same degree of safety against the rod becoming loose as the conventional anchoring elements. Moreover, a method for the manufacture thereof is to be provided.

The object is attained by an anchoring element according to Patent Claim 1 and by a method according to Claim 8. Further developments of the present invention are described in the dependent claims.

The anchoring element according to the invention is advantageous in that it is cheaper to manufacture, since the cutting of the thread is less resource-consuming from the point of view of manufacturing technology. Moreover, the height of the receiving part is reduced by the poorly defined runout thread teeth present in conventional anchoring elements.

Additional features and characteristics of the present invention are evident from the description of embodiments on the basis of the drawings.

The following is depicted in the figures:

Fig. 1 shows a sectional view of a first embodiment;

Fig. 2 shows a sectional view of a second embodiment; and

Fig. 3 shows a sectional view of a third embodiment.

Fig. 1 shows a monoaxial bone screw as a first embodiment of a bone anchoring element. The bone screw comprises a shaft 1 with a bone thread section and an essentially cylindrical receiving part 2 which is rigidly connected to the shaft and serves to receive a rod 100 of a given diameter D which connects the bone screw to additional bone screws. For this purpose, the receiving part 2 comprises a recess 3 with a U-shaped cross-section, said recess being dimensioned just large enough for rod 100 to be inserted and held by the channel formed by the base 4 of the recess and its side walls. The U-shaped recess 3 forms two legs 5, 6 whose free end 7 forms the upper edge of the receiving part. In the inserted state, in which the rod abuts on base 4 of the U-shaped recess, the surface of the rod is at a pre-determined distance A from the free end 7 of the receiving part.

An internal thread 8 extends from free end 7 along legs 5, 6 over a distance, which, in the embodiment shown, is equal to the pre-determined distance A. In the embodiment shown, the internal thread is provided as a metric thread. Adjacent to the internal thread is a recess or an undercut 9 which extends along the circumference and whose lower edge 10 facing away from the thread 8 resides at a distance B from free end 7 that is larger than the pre-determined distance A. Thus, the lower edge 10 of the undercut resides at a distance from base 4 of the recess that is smaller than the rod diameter D. In the embodiment shown, the upper edge 11 of the undercut facing the free end 7 resides at the level of the rod surface and thus resides at a distance A from the free end. It is preferred for the depth of the undercut to be equal to the depth of thread 8. The cross-section of undercut 9 is implemented to be essentially rectangular.

Moreover, a securing element in the form of an internal screw 12 with an outer thread engaging the internal thread is provided for the fixation of the rod in the receiving part.

In operation, the bone screw is screwed into the bone first followed by the insertion of the rod. Subsequently, the internal screw 11 is screwed in until its bottom side facing the rod presses onto the rod and fixes the rod in its position.

The manufacture of the bone screw preferably proceeds such that the undercut 9 in the receiving part is produced in a first step of the procedure and the thread 8 is applied in a second step of the procedure. This manufacturing process involves a smaller number of turns

of thread as compared to the conventional anchoring elements with thread runout. In contrast, these fewer turns of thread possess a well-defined profile and, thus, high load-bearing capacity. Consequently, the entire thread 8 can be shifted downwards in the direction of base 4 by the length of the weak runout thread teeth present in conventional anchoring elements with thread runout. As a result, the overall height of the receiving part is reduced as compared to the conventional anchoring elements. Moreover, the manufacture is cheaper, since the cutting of the thread is less work-intensive since there is no thread runout.

In a modification, the internal thread 8 extends from the free end 7 over a distance that is smaller than the pre-determined distance A such that the upper edge 11 of the undercut 9 resides above the rod surface when viewed in the direction of the free end 7 when rod 100 is in its inserted state. A further modification considers the undercut 9 to have rounded corners or the upper and lower edge of the undercut to be beveled.

Yet another modification considers the internal thread to be provided in the form of a buttress thread, in particular in the form of a buttress thread with a horizontal load-bearing flank, in the form of a flat thread with two horizontal flanks or in the form of a thread with a negative load-bearing flank angle rather than in the form of a metric thread. In this case, the internal screw 12 comprises a matching external thread. The threads can be provided in the form of right-hand or left-hand threads.

The second embodiment shown in Fig. 2 differs from the embodiment depicted in Fig. 1 in that an additional external thread 13 is provided on the free ends 5, 6 said external thread 13 extending to a pre-determined distance, when viewed from the direction of the free end 7 with the pre-determined distance being equal to distance A of the rod surface in the embodiment depicted. An undercut 14 is provided adjacent to the external thread, with the lower edge 15 of said undercut, which faces base 4, residing at a distance B' from the free end 7 that is larger than the pre-determined distance A. Preferably, the depth of the undercut is equal to the depth of the external thread. Moreover, an additional securing element is provided in the form of an external screw nut 16 which comprises an internal thread that engages external thread 13.

The operation is similar to that of the first embodiment except for the additional step, in which the external screw nut is screwed on as an additional securing element.

The manufacture of the anchoring element includes the additional steps – as compared to the first embodiment – of the application of the undercut 14 and external thread 13, whereby the undercut is generated first and the external thread subsequently, as in the previous procedure.

In a modification of the second embodiment, the length of the distance on which the internal thread 8 is provided differs from the length of the distance on which the external thread 13 is provided. It is crucial that the internal thread or the external thread extend from the free end 7 no further than to the level of the rod surface and that the lower edge of the undercut 9 or 13 is always below the rod surface. In a modification, the heights of the undercuts of the internal and external thread differ.

In a further modification, there is no internal thread and adjacent undercut and no internal screw as securing element, such that there is only the external thread and undercut adjacent to the undercut are provided. In a further modification, an undercut is provided adjacent to only one of the two threads, i.e. internal thread or external thread.

Moreover, all modifications described in relation to the first embodiment shall be equally applicable to the second embodiment.

Fig. 3 shows a third embodiment, in which the anchoring element is implemented as a polyaxial bone screw. The polyaxial bone screw comprises a screw element with a thread shaft 20 with a bone thread and a spherical segment-shaped head 21 which is connected to a receiving part 22. On one of its ends receiving part 22 is provided with a first bore 23 in an axially symmetrical alignment, whose diameter is larger than that of the thread section of thread shaft 20 and smaller than that of head 21. Moreover, receiving part 22 is provided with a coaxial second bore 24 which is open on its end opposite from the first bore 23 and whose diameter is sufficiently large for the thread section of the screw element to be guided through the first bore 24 and for the head 21 to be guided to the base of the second bore 23. A small coaxial section 25 is provided between the first bore and the second bore, said small coaxial section 25 being adjacent to the first bore 23 and being of spherical shape towards the open end, whereby its radius is essentially equal to that of the spherical segment-shaped section of head 21.

Receiving part 22 further comprises a U-shaped recess 26 which is arranged symmetrically with regard to the middle axis of the receiving part and serves for the insertion of the rod 100, whereby the base of the recess faces the first bore 23 and the recess forms two free legs 27, 28, whose free end 29 forms the upper edge of the receiving part.

An internal thread 30 and an external thread 31 are provided on legs 27, 28 adjacent to the free end 29 with the threads extending over a distance to a pre-determined distance from free end 29. Moreover, adjacent to the internal thread 30 and the external thread 31 there is an undercut 33, 34 on the side facing away from the free end 29.

Moreover, a cylindrical pressure element 35 is provided whose outer diameter is selected such that the pressure element can be inserted in the receiving part from the free end 29 of the legs and shifted within bore 24 towards the head 21. The end of the pressure element facing head 21 in its inserted state comprises a spherical segment-shaped recess 36 which widens towards that end and whose spherical radius is selected such that the pressure element surrounds head 21 from above when it is inserted in the receiving part. The opposite end of the pressure element comprises a U-shaped recess 37 whose dimensions are such that the rod 100 can be inserted and is held therein. In its state, in which the pressure element is inserted into the receiving part 22, the U-shaped recess 37 of pressure element 35 forms a channel, in whose base the rod rests. In the embodiment shown, the side walls of the U-shaped recess 37 of the pressure element do not protrude beyond the inserted rod. Moreover, the pressure element comprises a central bore 38 through which a screwing tool can be inserted to allow the screw element to be screwed in.

An internal screw is provided for the fixation of the head in its angular position and of the rod. Moreover, an external screw nut is provided for additional fixation.

In the assembled state of the anchoring element with the rod inserted and pressure element 35 pressing on the head, the surface of the rod resides at a distance A from free end 29 of the receiving part. In the embodiment shown, the internal thread 30 and the external thread 31 are dimensioned such that they extend to a position that is smaller than distance A when viewed from free end 29. The lower edge of the undercuts 33, 34 facing the base of the U-shaped recess 37 of pressure element 30 resides at a distance B from free end 29 that is larger than distance A between the rod surface and the free end.

In operation, the screw element is inserted in the receiving part in known fashion, then the pressure element is inserted and then the screw is screwed into the bone. Subsequently, the rod is inserted and the angular arrangement of the receiving part with regard to the screw element is adjusted and the rod is adjusted and then fixed by screwing in the internal screw and screwing on the external screw nut in known fashion.

The manufacture of the anchoring element is identical to the procedure of the first two embodiments with regard to the manufacture of the threads and undercuts of the receiving part.

In a modification that is similar to the modification of the second embodiment, the internal thread and external thread differ in length and/or the undercuts differ in height. All modifications of the first and second embodiments shall be equally applicable to the third embodiment.

# PATENT CLAIMS

1. Anchoring element for use in spinal or bone surgery with a shaft (1) for anchoring in a vertebra or bone section and an essentially cylindrical receiving part (2; 22) which is connected to the shaft and serves to connect to a rod (100) with a pre-determined diameter (D), whereby the receiving part (2; 22) comprises a U-shaped recess (3; 26) with a channel for the reception of the rod and two legs (5, 6; 27, 28) which are free on their end and comprise a thread (8, 13; 30, 31),
and with a securing element (12, 16) comprising a thread that engages the thread of the legs, whereby, with the rod inserted, the rod surface facing the free ends (7; 29) is at a pre-determined distance (A) from the free ends (7; 29) in axial direction,
characterized in that
the thread (8, 13; 30, 31) of the legs, when viewed from the free end, extends to a distance from the free end that is smaller than or equal to the pre-determined distance (A), and in that there is an undercut (9, 14; 33, 34) adjacent to the thread whose edge facing away from the thread resides at a distance (B, B') from the free end that is larger than the pre-determined distance (A).

2. Anchoring element according to Claim 1, characterized in that the depth of the undercut (9, 14; 33, 34) corresponds to the depth of the thread.

3. Anchoring element according to Claim 1 or 2, characterized in that the thread is an internal thread (8; 33) and the securing element is implemented as an internal screw (12).

4. Anchoring element according to anyone of the Claims 1 to 3, characterized in that the thread is an external thread (13; 34) and the securing element is implemented as a screw nut (16).

5. Anchoring element according to anyone of the Claims 1 to 4, characterized in that the thread (8, 13; 30, 31) is implemented as a metric thread, buttress thread, flat thread or as a thread with a negative load-bearing angle.

6. Anchoring element according to anyone of the Claims 1 to 5, characterized in that the connection between the shaft (1) and the receiving part (2) is implemented to be monoaxial.

7. Anchoring element according to anyone of the Claims 1 to 6, characterized in that the connection between the shaft (1) and the receiving part (2) is implemented to be polyaxial.

8. Method for the manufacture of an anchoring element according to anyone of the Claims 1 to 7, characterized in that the manufacture of the receiving part involves the manufacture of the undercut (9, 14; 33, 34) first and then the manufacture of the thread (8, 13; 30, 31).

SUMMARY

The invention provides an anchoring element for use in spinal or bone surgery with a shaft (1) for anchoring in a vertebra or bone section and an essentially cylindrical receiving part (22) which is connected to the shaft and serves to connect to a rod (100) with a pre-determined diameter (D), whereby the receiving part (22) comprises a U-shaped recess (26) with a channel for the reception of the rod and two legs (27, 28) which are free on their end and comprise a thread (30, 31), and with a securing element comprising a thread that engages the thread of the legs,

whereby, with the rod inserted, the rod surface facing the free ends (29) is at a pre-determined distance (A) from the free ends (29) in axial direction. The anchoring element is characterized in that the thread (30, 31) of the legs, when viewed from the free end, extends to a distance from the free end that is smaller than or equal to the pre-determined distance (A), and in that there is an undercut (33, 34) adjacent to the thread whose edge facing away from the thread resides at a distance (B) from the free end that is larger than the pre-determined distance (A). The anchoring element is cheap to manufacture and has a reduced overall height as compared to the known anchoring elements.

(Fig. 3)

Fig. 2

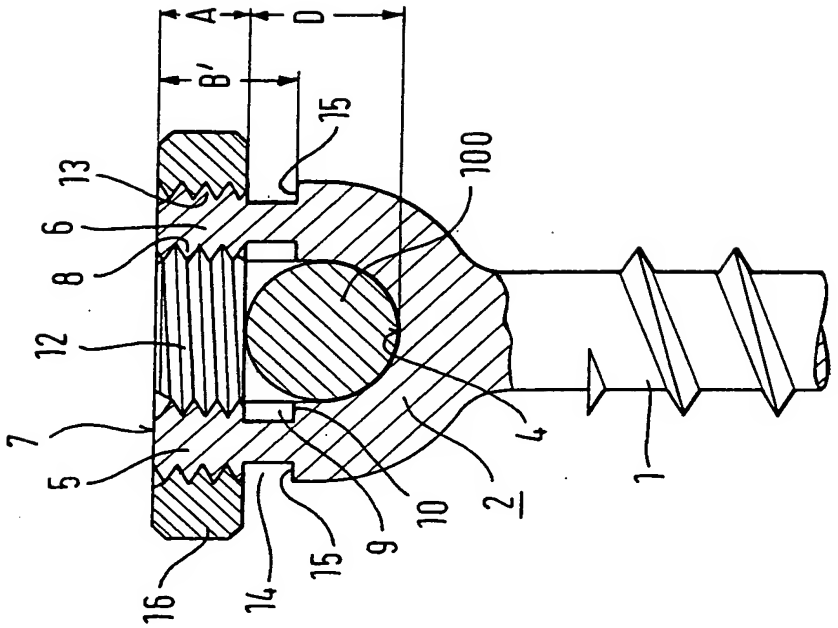


Fig. 1

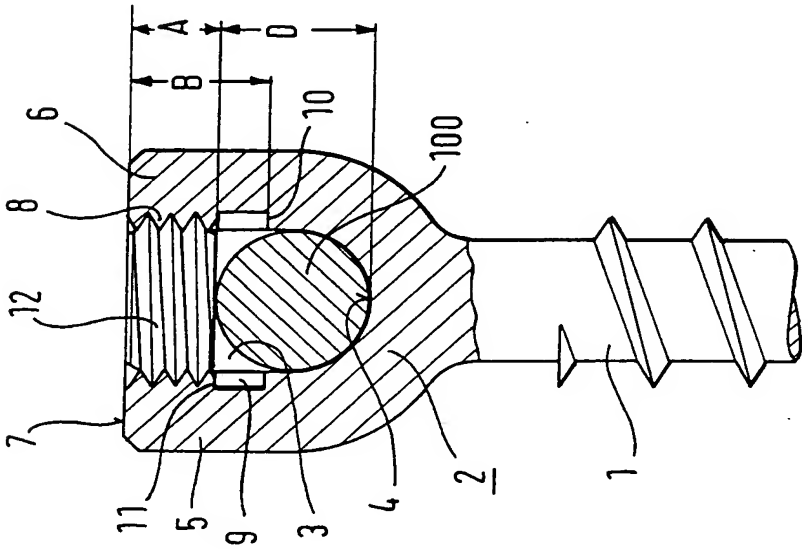

Fig. 3